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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/707,685 | 11/07/2000 | Julio C. Palmaz | 6006-015 | 9696 |

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EXAMINER

MILLER, CHERYL L

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

3738

DATE MAILED: 04/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/707,685

Applicant(s)

PALMAZ ET AL.

Examiner

Cheryl L. Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 and 24-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 14-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 November 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13 and 24-28, drawn to a stent structure with multiple structural elements, classified in class 623, subclass 1.15.

II. Claims 14-23, drawn to a method of making a stent by vacuum deposition, classified in class 427, subclass 2.1. The inventions are distinct, each from the other because of the following reasons:

2. Inventions I. and II. are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed in 1-13 and 24-28 can be made by another and materially different process such as dipping, painting, or welding. Because these inventions are distinct for the reasons given above and the search required for Group I. is not required for Group II., restriction for examination purposes as indicated is proper.

3. During a telephone conversation with David Rosenbaum (Registration No. 31,872) on 25 March 2002 a provisional election was made without traverse to prosecute the invention of II. (the method of making), claims 14-23. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-13 and 24-28 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Drawings

5. The drawings are objected to under 37 CFR 1.83(a) because they fail to show clearly defined reference numerals as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

6. Claims 17-23 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 17-19 and 21-22 recite "The method according to claim 13" in line 1 of each respective claim. It is suggested to change "The method according to claim 13" to recite --The method according to claim 14--. Claim 20 recites the limitation "the ion beam-assisted evaporative deposition" in lines 1 and 2. It is suggested to change "The method according to claim 19" to recite --The method according to claim 18--. Claim 23 is dependent upon claim 20 and inherits all problems associated with the claim.

Double Patenting

7. Claims 14-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 09/745,304. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined application only differs by adding the limitation of longitudinal and circumferential

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members to the independent claim. It is common knowledge in the art that most stents consist of longitudinal and circumferential members in order to provide flexibility and expansion. It would have been obvious to one having ordinary skill in the art at the time the invention was made to the limitation of longitudinal and connecting circumferential members to a stent in order to provide flexibility and expansion.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. The examiner has recognized there is at least one common inventor with the two applications. However, in the case of a double patenting rejection, the inventive entity must be the same in both applications. It appears there might be an error in the inventorship of at least one of the applications.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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9. Claims 14-20 and 22-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Roth (USPN 6,096,175). Roth discloses a method for manufacturing a stent, which includes all limitations recited in the claims. Referring to claim 14, Roth discloses a method of manufacturing a stent (col.4, lines 8-11) comprising steps of providing a substrate (36), (36+50), depositing a stent-forming metal onto the substrate by vacuum deposition (col.5, lines 35-38, 58-59; col.6, lines 8-11), and removing the substrate from the stent (col.5, lines 63-65; col.6, lines 3-4, 50-51). Roth discloses a stent that is radially expansible (col.2, lines 22-24, having longitudinal (26), (27), (28), and circumferential (32) interconnecting structural elements (fig.2).

Referring to claim 15, Roth discloses imparting a pattern onto the substrate surface (col.8, lines 3-8, 33-39).

Referring to claim 16, Roth discloses deposition of a metal onto the pattern (col.8, lines 8, 35-40, 55-62; col.9, lines 12-13).

Referring to claim 17, Roth discloses a sacrificial layer (50) on the substrate.

Referring to claims 18 and 19, Roth discloses deposition by ion beam evaporation or sputtering (col. 6, lines 19-36).

Referring to claims 20 and 23, Roth discloses deposition in the presence of an inert gas selected from the group consisting of argon, xenon, nitrogen, and neon (col.5, lines 34-40).

Referring to claim 22, Roth discloses a planar substrate (col.4, lines 19, 29; col.10, lines 21-22).

10. Claims 14-17 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Moller et al. (USPN 5,772,864). Moller discloses a method of manufacturing a stent, which includes all limitations recited in the claims. Referring to claim 14, Moller discloses a method of manufacturing an endoluminal stent (col.3, lines 7-10, 21-24; col.4, lines 10-13) capable of radial expansion (col.3, lines 27-28; col.5, lines 10-13, 21-22), having first structural elements defining a longitudinal axis and second structural elements defining a circumferential axis (fig.3, 7). Moller discloses a method comprising providing a

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substrate having an exterior surface (col.3, lines 28-30; col.5, lines 27-30), depositing a stent-forming metal onto the substrate by vacuum deposition (col.3, lines 30-31, 44-48; col.4, lines 38-40), and removing the substrate from the stent (col.3, lines 31-34, 49-50; col.11, lines 11-15).

Referring to claim 15, Moller discloses a step of imparting a pattern onto the substrate (col.3, lines 36-43; col.4, lines 60-63; col.5, lines 40-41, 45).

Referring to claim 16, Moller discloses a step of depositing a stent forming material onto a pattern (col.3, lines 45-48; col.4, lines 21-22, 65-67; col.7, lines 30-33).

Referring to claim 17, Moller discloses a deposition of a sacrificial layer onto the substrate (col.8, lines 54-60).

Referring to claim 21, Moller discloses a cylindrical substrate (fig.3).

11. Claims 14-17, 19, and 21-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Reed et al. (USPN 6,197,013). Reed discloses a method of manufacturing a stent, which includes all limitations recited in the claims. Referring to claim 14, Reed discloses a method of manufacturing an expandable stent (col.3, lines 59-61; col.4, lines 4-7; col.7, line 10), having longitudinal structural members and circumferential members (fig.2A). Reed discloses a method comprising providing a substrate (col.7, lines 17-19, 33; col.10, lines 62-63), depositing a stent forming material onto substrate by vacuum deposition (col.9, lines 44-54; col.10, lines 10-12, 66-67), and removal of substrate from stent (col.11, lines 4-5).

Referring to claim 15, Reed discloses a step of imparting a pattern onto the substrate (col.7, lines 52-53; col.8, lines 9-10, 40; col.9, lines 7-8).

Referring to claim 16, Reed discloses a step of depositing a stent forming material onto the substrate pattern (col.9, line 59; col.11, lines 2-3).

Referring to claim 17, Reed discloses a deposition of a sacrificial layer onto the substrate (col.9, lines 42-43).

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Referring to claim 19, Reed discloses a method conducted by sputtering (col.9, lines 51-54).

Referring to claims 21-22, Reed discloses a substrate of cylindrical and planar shape (col.10, lines 10-14, 62-63).

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

USPN 5,376,463 to Bak et al. discloses a method consisting of pattern placement onto a substrate, deposition of a metal onto the substrate, and removal of the metal from the substrate, the disclosed invention containing features related to claims 14, 15, 17, 18, and 20.

USPN 5,798,042 to Chu et al. discloses a biological filter made by pattern placement onto a substrate, application of a sacrificial layer to the substrate, application of a film, and removal of the sacrificial layer to release the film, the disclosed invention containing features related to claims 14-17.

USPN 6,322,588 B1 to Ogle et al. discloses a medical device made by pattern placement onto a substrate, masking the substrate, and deposition of a film, the disclosed invention containing features related to claims 15-19.

USPN 5,744,958 to Werne discloses various types of deposition and the benefits to each type.

USPN 4,444,848 to Shanefield et al. discloses a method of making a circuit board consisting of pattern placement onto a substrate, vacuum deposition of a metal onto the substrate, wherein sputtering or ion beam evaporation may be used.

USPN 5,849,206 to Amon et al. discloses a method of producing a stent comprising providing a substrate, and vapor depositing a metal coating onto the substrate in the presence of an inert gas, preferably argon.

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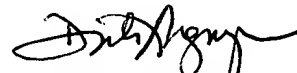
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl L. Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday-Friday, 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (703) 308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 746-7447 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Cheryl L. Miller
April 2, 2002


DINH X. NGUYEN
PRIMARY EXAMINER